IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL a corporation of Barbados,	)	
Plaintiff,	)	C.A. No. 05-586-KAJ
v.	)	(consolidated case)
ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION	)	**PUBLIC VERSION**
Defendants.	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 5,529,791

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Defendants Andrx Pharmaceuticals LLC and Andrx Corporation ("Andrx") submit this memorandum in support of their motion for summary judgment of non-infringement of U.S. Patent No. 5,529,791 ("the '791 patent"), asserted by plaintiff Biovail Laboratories International SRL ("Biovail") in this action.

I. INTRODUCTION

This is not a typical summary judgment motion in a patent case. Andrx does not ask the Court to construe any claim language or to wade through reams of deposition testimony and exhibits to find the facts. Rather, Andrx asks the Court simply to compare Biovail's infringement theory in this case to its infringement theory in a prior case against Andrx. The Court will find that Biovail is seeking to re-litigate the same case that it litigated and lost against Andrx several years ago.

Biovail here alleges infringement of the '791 patent based on Andrx's filing of an Abbreviated New Drug Application ("ANDA") for approval of a generic version of Biovail's CARDIZEM LA® diltiazem tablet. Biovail contends that the diltiazem drug pellets compressed to form Andrx's proposed tablet infringe the '791 patent. A critical limitation in all claims of the '791 patent requires a homogeneous admixture of a sugar and diltiazem salt. Biovail asserts that the Andrx diltiazem pellets meet the admixture limitation, if it is construed to cover an admixture that occurs after the pellets are *in vivo* or in the body. Biovail offers expert evidence of the alleged *in vivo* admixture.

As a matter of law, Biovail should be estopped from re-litigating its *in vivo* admixture theory. Biovail already litigated and lost the same issue, under the same patent, as to the same diltiazem pellets, and against the same defendant, Andrx. In that

prior case, the district court heard Biovail's evidence, and found that Biovail had failed to meet its burden of proving that the pellets formed the necessary admixture in the body. On appeal, the Federal Circuit expressly affirmed the district court's finding as to failure of proof, and further affirmed the legal conclusion that the Andrx pellets do not infringe the '791 patent.

Biovail already had its day in court to prove that the Andrx pellets create an admixture *in vivo*. Indeed, Biovail already had its day in the Federal Circuit to argue that the district court erred in finding Biovail's proof insufficient. Biovail cannot get around the finality of the Federal Circuit's decision by changing experts and offering their "new" expert evidence to support the same theory. Biovail's right to submit evidence in support of its *in vivo* admixture theory ended when Biovail rested its case at trial the first time. Biovail is estopped from re-opening what the district court and Federal Circuit closed.

Finally, Andrx is entitled to summary judgment of no infringement, because Biovail's expert evidence in support of it *in vivo* theory is Biovail's only evidence that Andrx's pellets meet the admixture limitation of the '791 patent. Biovail has not produced any evidence of the essential admixture in Andrx's pellets outside the body.

II. FACTS

This is a case under the Hatch Waxman Act, which creates jurisdiction to hear patent disputes between a patentee brand name drug company and a potential competitor that files an ANDA seeking approval of a generic version of the brand name drug. Andrx filed ANDA No. 77-686 for approval of a generic version of Biovail's CARDIZEM LA® tablet, with the active ingredient diltiazem.

As part of its ANDA, Andrx certified to the FDA that its proposed generic tablet would not infringe any valid and enforceable claim of the '791 patent, which had been listed by Biovail in the FDA "Orange Book." Andrx served the factual and legal basis for that certification on Biovail on June 22, 2005. Biovail filed this action on August 10, 2005, alleging infringement of the '791 patent.[1]

Biovail bases its infringement case on the tiny extended release diltiazem drug pellets that are compressed to form Andrx's proposed generic version of Biovail's CARDIZEM LA® diltiazem tablet. Andrx chose to use these pellets for a reason – namely, that Biovail previously had litigated and lost the issue of whether the same Andrx pellets infringed the '791 patent, when used in Andrx's generic version of Biovail's TIAZAC® diltiazem capsule. *See Biovail Corp. Int'l v. Andrx. Pharmaceuticals, Inc.*, 158 F. Supp. 2d 1318 (S.D.Fla. 2000), *aff'd*, 239 F.3d 1297 (Fed. Cir. 2001) (hereinafter "the TIAZAC® case").[2]

As set forth in the declaration of Redacted

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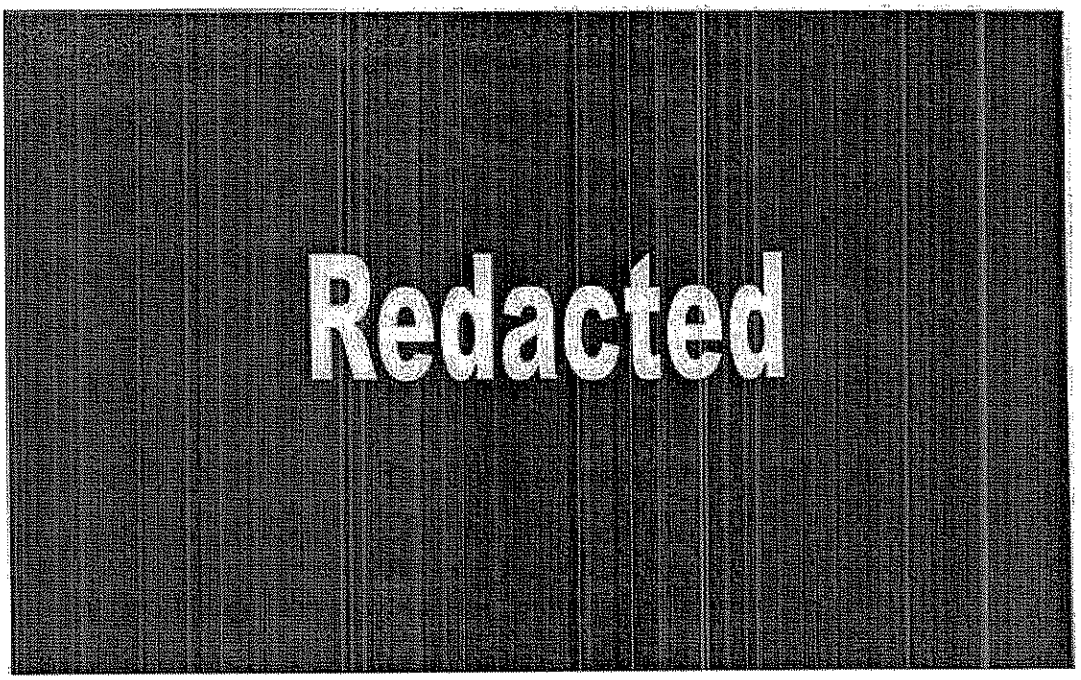
[1] Biovail recently consolidated this action with another Hatch Waxman Act complaint, alleging that Andrx's proposed generic diltiazem tablet in this case infringes a newly-issued patent. This motion, however, is directed solely to the '791 patent, regarding which Biovail has served its expert evidence of infringement.

[2] For the Court's convenience, Andrx has provided copies of these decisions at Exhibits A and B to the Declaration of Steven Maddox in Support of Defendants' Motion for Summary Judgment of Non-Infringement of U.S. Patent No. 5,529,791 ("Maddox Decl."), which is attached hereto as Exhibit 1.



Just as in the prior TIAZAC® case, Biovail does not offer any evidence that the Andrx pellets, as manufactured, meet a critical limitation of all claims of the '791 patent. That limitation calls for "one or more diltiazem salts and an effective amount of a wetting agent in admixture … and wherein the wetting agent is selected from the group consisting of sugars." Ex. 1, Maddox Decl. at Ex. C (the '791 patent). As applied by Biovail to the Andrx pellets, this "admixture" limitation requires a homogeneous admixture of the sugar in the inert seed core and the diltiazem hydrochloride in the drug layer. Conspicuously absent from Biovail's expert reports is any testimony that Redacted

Redacted

And again, just as it did in the previous TIAZAC® case, Biovail attempts to overcome this lack of evidence by arguing that the sugar and diltiazem of the Andrx pellets form a homogeneous admixture when *in vivo* -- that is, once the pellets are

ingested into the body, and in the aqueous environment of the gastrointestinal tract.[3] In the TIAZAC® case, Biovail offered expert evidence of the alleged *in vivo* admixture, based on dissolution studies and Scanning Electron Micrographs (SEMs) analyses. *See Biovail*, 158 F. Supp. 2d at 1326-27; *see also* Ex. 1, Maddox Decl. at Ex. D (Biovail's Appellate Brief at 36-38). Here again in this case, Biovail offers expert evidence of the same alleged *in vivo* admixture, again based on various dissolution studies and SEMs.[4] The names of the experts have changed, and Biovail has tossed in some additional tests, but the fundamental evidence and issue is the same: whether the Andrx pellets form a homogeneous admixture of sugar and diltiazem, once inside the body.

That issue was fully and finally resolved in the TIAZAC® case. The district court expressly found that Biovail's expert evidence failed to meet Biovail's burden of proving the requisite *in vivo* homogeneous admixture. "Biovail has failed to prove that an admixture between the sugar and the diltiazem forms in the body." *Biovail*, 158 F. Supp. 2d at 1326. The district court even made detailed factual findings as to why Biovail's evidence was unreliable and insufficient. *Id.* at 1326-27.

The Court of Appeals for the Federal Circuit rejected Biovail's challenges to the district court's findings and conclusion. Indeed, the Federal Circuit affirmed the judgment of no literal infringement based solely on Biovail's failure to prove that

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[3] For purposes of this motion only, Andrx applies Biovail's construction of the claim term "admixture" to include what occurs after the pellets are introduced into the aqueous environment *in vivo* or inside the body. Similarly, Andrx accepts for purposes of this motion Biovail's contention that the inner sugar seed core of the Andrx pellet is a "wetting agent."

[4] Redacted Ex. 1, Maddox Decl. at Exs. E and F, respectively

Andrx's pellet formed a homogeneous admixture of sugar and diltiazem after being ingested into the body. *Biovail*, 239 F.3d at 1303.

III. ARGUMENT

The doctrine of collateral estoppel precludes a party from re-litigating an issue that was litigated, determined, and essential to a final judgment in a prior action. *Witkowski v. Welch*, 173 F.3d 192, 199 (3d Cir. 1999); *Electro-Miniatures Corp. v. Wendon Co.*, 889 F.2d 41, 44 (3d Cir. 1989). Estoppel is a matter of regional circuit law. *Dana v. E.S. Originals, Inc.*, 342 F.3d 1320, 1327 (Fed. Cir. 2003). The Third Circuit has identified four essential factors for collateral estoppel to apply. All four of those factors are present in this case. None is subject to any genuine dispute.

(1) the issue at stake is identical to the one involved in the prior litigation;

(2) the issue was actually litigated in the prior suit;

the determination of the issue in the prior suit was a critical and necessary part of the judgment in that action; and

the party against whom the earlier decision is asserted had a full and fair opportunity to litigate the issue in the earlier proceeding.

Henglein v. Colt Indus., 260 F.3d 201, 209 (3d Cir. 2001); *Burlington N.R.R. v. Hyundai Merchant Marine Co.*, 63 F.3d 1227, 1232 (3d Cir. 1995).

First, the issue at stake here is identical to the issue in the TIAZAC® case. It is the issue of whether the same Andrx pellets form a homogeneous admixture in the body sufficient to meet the "admixture" limitation in all claims of the '791 patent. Biovail has asserted the same patent in both cases, based on the same *in vivo* theory as to how the same Andrx pellets allegedly meet the same "admixture" claim limitation. Andrx's manufacturing documents confirm that Redacted

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Second, the issue was actually litigated in the prior suit. Biovail litigated the issue both at trial and on appeal to the Court of Appeals for the Federal Circuit. *See Biovail*, 158 F. Supp. 2d at 1326-27; *Biovail*, 158 F.3d at 1302-3; *see also* Ex. 1, Maddox Decl. at Ex. D (Biovail's Appellate Brief at 32-39).

Third, determination of the issue was a critical and necessary part of the judgment in the prior action. Biovail's failure to prove a homogeneous admixture in the body was a critical and necessary part of the final judgment by the Court of Appeals for the Federal Circuit. Indeed, the Court explained that Biovail's failure of proof as to an *in vivo* admixture obviated the need to resolve Biovail's other contentions on appeal. The judgment would be affirmed even if the Court accepted Biovail's other contentions on appeal:

> The district court in this case analyzed a significant amount of scientific evidence and made factual findings based on that evidence.
>
> Regardless of its construction of the limitation "wetting agent," **the district court found Biovail failed to prove by a preponderance of the evidence that the "sugar" in Andrx's product forms a homogeneous admixtures with diltiazem in the body. Because this finding was clearly supported by the evidence**, it does not leave this court with a "definite and firm conviction that a mistake has been committed."
>
> Therefore, even assuming *arguendo* that "admixture" is not limited to dry state compositions and that sugar as used in Andrx's product was a "wetting agent," **the district court's determination that Andrx's product does not**

literally infringe claim 1 of the '791 patent was not clearly erroneous.

Biovail, 239 F.3d at 1303 (emphasis added).

Fourth, Biovail had a full and fair opportunity to litigate the issue in the TIAZAC® case. Biovail not only had, but actually took that opportunity to litigate this issue at trial and appeal. *See Biovail*, 158 F. Supp. 2d at 1326-27; *Biovail*, 158 F.3d at 1302-3; Ex. 1, Maddox Decl. at D (Biovail's Brief On Appeal at 32-39).

To the extent that Biovail seeks to offer new evidence or analyses of the pellets, it is well settled that collateral estoppel "cannot be avoided simply by offering evidence in the second proceeding that could have been admitted, but was not, in the first." 18 CHARLES ALLEN WRIGHT & ARTHUR R MILLER, FEDERAL PRACTICE AND PROCEDURE § 4416 (2000). Indeed, Biovail itself was party to a case in which the court held a brand drug company collaterally estopped from presenting new evidence on an issue that it previously had litigated in an earlier Hatch Waxman Act case against the same generic drug company. *See Bayer AG v. Biovail Corp.*, 2001 US Dist LEXIS 23907 at *25 (N.D.Ga. Mar. 27, 2001) (attached hereto at Ex. 3).

IV. CONCLUSION

Biovail should be estopped from re-litigating whether the pellets comprising Andrx's proposed generic tablet, once ingested in the body, meet the "admixture" claim limitation necessary to infringe the '791 patent. Further, because Biovail has not produced any evidence that the pellets meet the "admixture" limitation outside of the body, the Court should grant summary judgment of no infringement.

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CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on November 29, 2006, the attached document was hand-delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF.

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